

Claims

1. A pharmaceutical composition comprising an ACE inhibitor, or a pharmaceutically acceptable salt or derivative thereof, and a C₁₆-C₂₈ glyceride.
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2. A pharmaceutical composition of claim 1, comprising 5-30% by weight C₁₆-C₂₈ glyceride.
3. A pharmaceutical composition of claim 1 or 2, comprising one or more
10 further excipients which are compatible with the ACE inhibitor or the pharmaceutically acceptable salt or derivative thereof.
4. A pharmaceutical composition of claim 3, wherein the one or more further excipients are selected from hydroxypropylmethylcellulose, pregelatinised starch,
15 microcrystalline cellulose, lactose, sodium starch glycolate, sodium stearyl fumarate, red ferric oxide and yellow ferric oxide.
5. A pharmaceutical composition of any one of the preceding claims, comprising:
20 2-6% by weight ACE inhibitor,
10-15% by weight C₁₆-C₂₈ glyceride,
65-75% by weight lactose anhydrous,
10-15% by weight sodium starch glycolate,
0.5-2% by weight sodium stearyl fumarate,
25 0-0.4% by weight yellow ferric oxide, and
0-0.1% by weight red ferric oxide.
6. A pharmaceutical composition of any one of the preceding claims, wherein the pharmaceutical composition is stable.
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7. A pharmaceutical composition of any one of the preceding claims, suitable for direct compression into tablets.

8. A pharmaceutical composition of any one of the preceding claims, wherein the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, and the C₁₆-C₂₈ glyceride form a mixture.
- 5 9. A pharmaceutical composition of any one of the preceding claims, wherein the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, the C₁₆-C₂₈ glyceride and one or more further excipients form a mixture.
- 10 10. A pharmaceutical composition of claim 8 or 9, wherein the mixture is an intimate mixture.
11. A pharmaceutical composition of any one of claims 8 to 10, wherein the mixture is suitable for direct compression into tablets.
- 15 12. A pharmaceutical composition of any one of claims 1 to 7, comprising granules or particles comprising the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, wherein the granules or particles comprise a coating comprising the C₁₆-C₂₈ glyceride.
- 20 13. A pharmaceutical composition of any one of the preceding claims, further comprising a β -blocker, a diuretic, a calcium-channel blocker, a vasodilator anti-hypertensive drug, or an angiotensin II receptor antagonist.
- 25 14. A pharmaceutical composition of any one of the preceding claims, wherein the composition is suitable for oral, parental, transdermal, airway, rectal, vaginal or topical administration.
15. A pharmaceutical composition of any one of the preceding claims, wherein the composition is suitable for oral administration.
- 30 16. A pharmaceutical composition of claim 15, wherein the composition is in unit dosage form comprising 1-20mg of the ACE inhibitor or the pharmaceutically acceptable salt or derivative thereof.

17. A pharmaceutical composition of claim 15 or 16, wherein the composition is provided in the form of a tablet, capsule, caplet, troche, lozenge, dragée, powder, granules or particles.
- 5 18. A pharmaceutical composition of claim 17, wherein the tablet, capsule, caplet, troche, lozenge, dragée, powder, granules or particles comprise a coating comprising the C₁₆-C₂₈ glyceride.
- 10 19. A pharmaceutical composition of any one of claims 15 to 18, wherein the composition is provided in the form of a tablet.
20. A pharmaceutical composition of claim 19, wherein the tablet has a disintegration time of not more than 10 minutes.
- 15 21. A pharmaceutical composition of claim 19 or 20, wherein the tablet has a shelf-life of at least 5 years.
22. A pharmaceutical composition of any one of the preceding claims, substantially as hereinbefore described with reference to the description.
- 20 23. A pharmaceutical composition of any one of the preceding claims, for use as a medicament.
- 25 24. A pharmaceutical composition of claim 23, for use as a medicament for the treatment or prevention of a cardiovascular disease, a coronary heart disease, a cerebrovascular disease, a peripheral vascular disease, arrhythmia, hypertension, cardiac failure, cardiovascular death, myocardial infarction, stroke or angina.
- 30 25. A method of treating or preventing a cardiovascular disease, a coronary heart disease, a cerebrovascular disease, a peripheral vascular disease, arrhythmia, hypertension, cardiac failure, cardiovascular death, myocardial infarction, stroke or

angina, comprising administering an effective amount of a pharmaceutical composition of any one of claims 1 to 24 to a patient in need thereof.

26. Use of a pharmaceutical composition of any one of claims 1 to 24 in the manufacture of a medicament for the treatment or prevention of a cardiovascular disease, a coronary heart disease, a cerebrovascular disease, a peripheral vascular disease, arrhythmia, hypertension, cardiac failure, cardiovascular death, myocardial infarction, stroke or angina.

27. A method of preparing a pharmaceutical composition of any one of claims 1 to 24, comprising the step of blending the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, with the C₁₆-C₂₈ glyceride.

28. A method of claim 27, wherein the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, and the C₁₆-C₂₈ glyceride are blended to form an intimate mixture.

29. A method of claim 27 or 28, comprising the step of blending the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, with the C₁₆-C₂₈ glyceride and one or more further excipients.

30. A method of claim 29, comprising the steps of blending the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, with the C₁₆-C₂₈ glyceride to form a pre-mix, and blending the pre-mix with one or more further excipients.

31. A method of claim 29 or 30, wherein the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, the C₁₆-C₂₈ glyceride and one or more further excipients are blended to form an intimate mixture.

32. A method of any one of claims 27 to 31, further comprising the step of compressing the blend of the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, and the excipient(s) into tablets by direct compression.

33. A method of claim 32, further comprising the step of providing the tablets with a coating comprising the C₁₆-C₂₈ glyceride.

5 34. A method of preparing a pharmaceutical composition of any one of claims 1 to 24, comprising the steps of preparing granules or particles comprising the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, and optionally one or more excipients, and providing the granules or particles with a coating comprising the C₁₆-C₂₈ glyceride.

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35. A method of any one of claims 27 to 34, wherein the pharmaceutical composition is prepared in batches of 5-150kg.

36. A method of providing a stable pharmaceutical composition comprising an
15 ACE inhibitor or a pharmaceutically acceptable salt or derivative thereof, the method comprising incorporating a C₁₆-C₂₈ glyceride into the composition.

37. A method of claim 36, comprising incorporating the C₁₆-C₂₈ glyceride into
20 the composition in a mixture with the ACE inhibitor or the pharmaceutically acceptable salt or derivative thereof.

38. A method of claim 37, comprising incorporating the C₁₆-C₂₈ glyceride into
the composition in an intimate mixture with the ACE inhibitor or the
25 pharmaceutically acceptable salt or derivative thereof.

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39. Use of a C₁₆-C₂₈ glyceride to provide a stable pharmaceutical composition comprising an ACE inhibitor or a pharmaceutically acceptable salt or derivative thereof.

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40. A method of any one of claims 36 to 38, or a use of claim 39, wherein the pharmaceutical composition is stabilised to minimize the degradation of the ACE inhibitor or the pharmaceutically acceptable salt or derivative thereof.

41. A pharmaceutical composition, a method or a use of any one of the preceding claims, wherein the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, is susceptible to heat and/or mechanical stress-induced degradation.

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42. A pharmaceutical composition, a method or a use of claim 41, wherein the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, is ramipril, trandolapril, quinapril, or a pharmaceutically acceptable salt or derivative thereof.

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43. A pharmaceutical composition, a method or a use of claim 42, wherein the ACE inhibitor, or the pharmaceutically acceptable salt or derivative thereof, is ramipril or a pharmaceutically acceptable salt or derivative thereof.

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44. A pharmaceutical composition, a method or a use of any one of the preceding claims, wherein the glyceride comprises one, two or three C_{16} - C_{28} acyl moieties, wherein each C_{16} - C_{28} acyl moiety is independently of the formula $-CO-R$, wherein R is a saturated or unsaturated hydrocarbon, which contains from 16 to 28 carbon atoms, and which is straight-chained or branched.

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45. A pharmaceutical composition, a method or a use of claim 44, wherein R is a saturated hydrocarbon and/or wherein R is a straight-chained hydrocarbon.

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46. A pharmaceutical composition, a method or a use of any one of the preceding claims, wherein the glyceride is a C_{18} - C_{26} glyceride.

47. A pharmaceutical composition, a method or a use of claim 46, wherein the glyceride is a C_{20} - C_{24} glyceride.

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48. A pharmaceutical composition, a method or a use of any one of the preceding claims, wherein the glyceride comprises at least 50% diglyceride.

49. A pharmaceutical composition, a method or a use of any one of the preceding claims, wherein the glyceride is glycerol dibehenate.

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